THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 2 1999

The Honorable Don Nickles
United States Senate
133 Hart Senate Office Building
Washington, DC 20510

Dear Senator Nickles:

Thank you for your letter dated February 11, 1999, concerning the recent announcement by the Director of the National Institutes of Health (NIH) regarding federal funding for research utilizing human pluripotent stem cells. As you know, this research has the potential to lead to great progress in our treatment of debilitating and deadly diseases, our understanding of human development and our ability to develop and test new drugs. Stem cell research is richly promising, yet raises important ethical issues. Therefore, Dr. Varmus and his colleagues at the National Institutes of Health (NIH) will proceed with great caution to ensure that the highest standards are set before moving forward in this area.

In keeping with the significant ethical concerns that must be considered, the NIH plans to proceed in a careful and deliberate fashion to develop rigorous guidelines. A working group of the Advisory Committee to the Director of NIH will develop guidelines for the conduct of research using pluripotent stem cells and will recommend an oversight mechanism for protocol review. The National Bioethics Advisory Commission is studying these issues and will provide us with advice that -- together with counsel from outside experts, Congress and the public -- will help ensure appropriate oversight.

First and foremost, these guidelines will ensure that any research funded in this area is consistent with the prohibition on federal funding for human embryo research contained in section 511 of the HHS appropriations law. Since this prohibition was first enacted in 1996, the Department of Health and Human Services (HHS) has conscientiously adhered to its strictures. For example, we have included the restriction on the use of funds in the NIH Grants Policy Statement and have issued notices reminding NIH intramural staff and the extramural research community that they must observe the prohibition. When necessary, we have not and will not hesitate to take appropriate enforcement action. I am firmly committed to our continued adherence to this law.

You have asked whether pluripotent stem cells may come together in culture to begin developing as an embryo. The scientific knowledge base about pluripotent stem cells comes from years of experience in animal research. Mouse pluripotent stem cells grown in a petri dish can give rise to specialized cells and tissues which sometimes form an aggregated structure, similar to certain tumors of the ovary and testis, termed an "embryoid body." These mouse embryoid bodies, however, are not embryos. Similarly, in one report on the derivation of human pluripotent stem cells, researchers observed that the human pluripotent stem cells can form embryoid bodies that are similar in structure to mouse embryoid bodies, which, as noted above, are not embryos.

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I have reviewed our Department's position and am reassured that proceeding cautiously with research on existing pluripotent stem cell lines is both legal and appropriate. Further, it will allow the NIH to foster world-class research on stem cells, assure appropriate oversight of such research, and bring together the finest minds and facilities to further medical and scientific advances. I assure you that the NIH understands and respects the deep convictions of people in the academic, religious and bioethics communities, and in Congress, and intends to seek the advice and comment of those communities as we move ahead. I look forward to working with you to ensure that the legal and ethical issues involved in this extremely promising area of research are addressed.

Sincerely,

Donna E. Shalala